TISSUE AND IMPLANT PRODUCT SUPPLY SYSTEM AND METHOD

FIELD OF THE INVENTION

This invention relates to a supply system and method of harvesting, inventorying, selecting and delivering tissue and implant products, with optional governmental, reporting and associated hardware including a mobile hand held electronic user device that synchronizes with a base system including features which provide feedback to the base system regarding the supplied product.

BACKGROUND OF THE INVENTION

Medical procedures involving implantation of replacement tissue and devices have unique product supply requirements. For live tissue, there are supply issues including locating donors and keeping donated tissue alive, delivering and inventorying live tissue, as well as determining criteria for use of the tissue in a living patient. For this and other types of implants and tissue, there are further issues concerning size, shape, availability, surgical techniques, and after implantation monitoring. Finally, there are sales, accounting, and government regulatory reporting requirements. While many systems exist which address these issues, none provide an integrated solution which supports the user in the

field, typically a sales/marketing representative or a representative of a provider of implant/tissue services.

SUMMARY OF THE INVENTION

The present invention provides a tissue and implant product acquisition and supply system which supports users in the field with a wireless phone line modem web served or free standing mobile hand-held device (hereinafter for ease of description as "wireless hand held electronic device") that synchronizes with a base system, such as a personal computer, private/public network based system, Web-server, etc.

FIG. 1 illustrates one embodiment of a typical tissue and implant supplier's interface for a wireless hand held electronic device, e.g. a hand-held personal digital assistant. It is to be understood that such a device provides typical user options such as e-mail, voice messaging, personal lists, etc. This embodiment provides not only a conduit for channeling user requests to a supplier and responses from the supplier but also provides an extensible support infrastructure by capturing requirements, assisting in harvesting and tracking, including, for example, height/weight and body mass, deformalities or abnormalities of the donor, placing orders, managing catalogs and inventory, in addition to delivering messages and providing e-mail and facsimile, etc., in

the hand-held's databases; and synchronizing with databases of suppliers' base systems. The availability of products, feedback on storage and use of products, and other essential information is kept up-to-date, including confirmation of orders placed and is always accessible by end-users in the supply system of the present invention.

Because of the unique procedural and specification requirements of tissue products and implants, the wireless device can be used to provide camera images of a target site to a supplier before, during and after surgery. The camera can, thus, be used to document the condition of tissue or implant immediately before and/or during or after surgery. Further, a Measuring System (such as the device of U.S. Patent No. 5, 832,422 to Wiedenhoefer the entire specification of which is hereby incorporated by reference as if explicitly set forth herein) can provide a set of precise measurements of the target to facilitate the selection of a tissue product or implant. Finally, a supplier can provide video output to the hand-held, e.g., to educate a surgeon in the use of a new device or to provide x-rays or CT/MRI scans, including a measurement marker on the x-ray or a reference scale on the CT/MRI scan so that the user can determine at least one of a size of the implant or tissue or any object in the image of any segment thereof

or angle on the image. The foregoing are meant as exemplary embodiments only and not in any limiting sense.

Once a tissue product or device has been implanted, the product is assigned to a patient record and the patient receiving the product can be monitored and base system inventory can be adjusted by updating the databases resident on the supplier's base station during a synchronization operation.

In such an embodiment, data regarding transactions involving products provided by suppliers is captured in databases stored in the wireless mobile hand-held device and these hand-held databases are synchronized with corresponding supplier databases stored on Web-servers, personal computers, etc., of supplier systems.

The present invention is thus a resource tool for medical provider users and supplier sales/marketing representatives alike. Using the present invention, up-to-date product information is instantly accessible through wireless communications or Phone Line modem , even to a surgeon performing surgery in an operating room. Additional advantages are the automation of the documentation and accounting processes between medical suppliers and medical facilities. Such advantages include, for example, an automated accounting process which results in a reduction of data input errors and unrecorded inventory movement. The invention can assist in providing expedited patient diagnosis, up to date product

information and automated governmental reporting. It may also be used to show to potential donor families a high standard for care for the movement of donated tissues and may result in improvements in acquisition and distribution of precious donor tissue resulting in increased amounts of donor to patient activity. FIG. 5 is a table summarizing the supporting features of the present invention and the benefits that accrue to users as a result of these features.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a supplier's user interface hierarchy provided on a wireless mobile hand-held device.

FIG. 1a illustrates a supplier menu of level 1 of the interface hierarchy illustrated in FIG. 1.

FIG. 2 illustrates normal inventory routes between components of a product Supply Chain and Medical Services Provider.

FIG. 3 illustrates objects of databases resident in the wireless mobile hand-held device.

FIG. 4 is a flow sheet of a method of use; and

FIG. 5 is a table summarizing the supporting features of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 illustrates a preferred embodiment of a supplier's user interface that may be provided on a wireless mobile hand-held device for use by a community of users including personnel of at least one Medical Services Provider and at least one Supply Chain of tissue and implant products. As used in the specification and claims, the term "tissue" is meant to include animal, including human, tissue, as well as synthetically manufactured materials, e.g., grafts. As illustrated in FIG. 2, a supplier of products is typically a chain of at least an independent Tissue Recovery Organization and an independent Product Supplier. External or third party suppliers as well as independent Sales Representatives and Distributors can also participate in a particular Supply Chain. Medical Services Providers comprise user organizations, such as hospitals including surgeons, clinics, or the like that interact with the Product Supply Chain components as illustrated in FIG. 2.

USER COMMUNITY

In a preferred embodiment, the wireless interface device is intended to be shared by multiple user types and therefore user administration capabilities are provided to manage access by authorized users. Various types of users are supported, comprising:

- Primary supplier:

i. Supplier employee,

ii. Distributor-agent - interacts with sales representatives and supplier employees and transactions involve logistics of product inventory, and

iii. sales representative - assists surgeons, doctors, and clinical staff in product selection and usage, interacts with other sales representatives and distributors resulting in multiple inventory transactions;

- Tissue recovery organization - works independently of a medical facility to generate donor availability and harvest bone and tissue and is also responsible for completing governmental documentation and required reports;
- Independents:

i. Distributor - interacts with sales representatives and third party suppliers resulting in transactions involving the logistics of product inventory, and

ii. Sales representative - interacts with medical staff, clinical staff, other sales representatives and distributors resulting in multiple inventory transactions;

- Medical Services Provider:

  i. Consignment - the staff responsible for receiving and maintaining supplier-owned products that are physically stored at the Medical Services Provider's facilities and supplying this product when requested by others, resulting in multiple inventory transactions,

  ii. Facility - the clinical staff manages inventory at each independent medical facility monitoring product inventory levels, requesting replenishment of product as necessary directly from the sales representatives' on-hand inventory, a distributor, or directly from suppliers; while in the operating room the medical staff may request product directly from the medical facility's inventory and it is the responsibility of the clinical staff to fill the surgeon's request; clinical staff also comes into contact with patients and assigns product to patient records, and

  iii. Medical staff - never requests product directly from a supplier but employs the Measuring System, or a like subsystem, to provide detailed physical requirements and when in surgery requests product

directly from the sales representatives' on-hand inventory or the consignment inventory of the medical facility resulting in multiple inventory transactions;

- Third party or external supplier - interacts with all users resulting in multiple inventory transactions.

Inventory data is reported and tracked on multiple wireless mobile hand-held devices as users interact with one another, the possible interactions being illustrated in FIG. 2. For example, as described above, a Medical Facility may request product directly from a sales representative, on-hand inventory (consignment), a distributor-agent or directly from the supplier. However, in this embodiment, the medical staff never requests product directly from the supplier. Consignment inventory is owned by the supplier but resides in the facilities of and is managed by a Medical Services Provider.

SUPPLIER DATABASES

The supplier maintains several different databases on a base system, which is a Web-server, in a preferred embodiment.

1. product information database - is accessible by the wireless mobile hand-held device user and is administered so that access is restricted and the data is categorized and stored at

least in one of the following registries: user, account, menu, product, order, inventory.

2. information database - is accessible by the wireless mobile hand-held device user and contains information that the supplier wishes to communicate to individuals who promote, distribute and track the supplier's products.

From the databases the operator can track any request for a user of the mobile hand held devices, such as inventory or ordering requests. The operator can, therefore, profile the user to and in use of the system, e.g., to anticipate the type and number of tissue/implants that a user may require in the future.

MOBILE DATABASES

Three types of objects, as illustrated in FIG. 3, can reside in the databases of each wireless mobile hand-held device:

- synchronized objects 30 - objects that are subject to being automatically synchronized to match the objects in the supplier's database;
- transaction objects 31 - objects that are designed to carry the content of a transaction from the databases of the wireless mobile hand-held device to the supplier's databases; and
- personal objects 32 - objects that are maintained only by the user of the wireless mobile hand-held device.

MOBILE HAND-HELD SYSTEM

FIG. 1 illustrates a preferred embodiment of a system, according to the present invention, that is provided to a user of a wireless mobile hand-held device. A hierarchy of screens is illustrated in FIG. 1, with the first level 10 providing a menu of major functions available to the user, as illustrated in FIG. 1a:

- Products 11 - product selection menu organized by product type
- Measurement System 12 - interface to an implementation of a measurement system, as described in U.S. Patent No. 5,832,422, which allows precise measurements to be obtained from images such as x-rays CT/MRI Scans or directly on Patient
- Help 13
- Synchronize 14 - synchronize pending information
- Inventory 15 - inventory selection menu that comprises: List, Receive, Release, Reconcile and Read Bar Code
- Supplier Message 16 - broadcasted messages from a supplier
- Options 17
- Order 18
- Camera 19

Both Bar Code (Inventory) and Camera functionality require a hardware device to be physically interfaced with the hand-held device and software to be installed to capture and process the inputs from these devices. These interfaces can be accomplished in a well known manner. Other functionality provided by the wireless mobile hand-held system comprises e-mail, facsimile, date selection, donor recovery, personal lists, as well as other functionally dedicated software or plug-compatible subsystems, e.g., an audio recorder or a modem.

By way of example only, in contrast to the hardware plugin approach of the device of U.S. Patent No. 5,832,422, one such functionally dedicated subsystem employs the screen of the wireless mobile hand-held device to display an image of a target for tissue or implantation. The subsystem receives input from a user who indicates an area of the image data from this area of the target image is then subjected to processing, as selected by the user, to derive, e.g., adjusted measurements for product selection, customization, specification, and the like, and provide wireless/modem transmission of adjusted measurements.

SUPPLIER BASE SYSTEM

In a preferred embodiment a supplier's base system is a Web-server that provides end user functionality and system administration services, comprising:

- login/logout
- backup mobile settings
- restore mobile settings
- synchronize products
- synchronize accounts
- synchronize menus
- synchronize inventories
- synchronize messages
- new delivered order
- new request order
- receive inventory
- release inventory
- reconcile inventory
- new e-mail message
- new facsimile message
- put menus
- add user
- remove user
- update user
- add product
- remove product
- update product
- add account

- remove account
- update account
- new message

Each of these functions is activated, in a preferred embodiment, by a "request" Electronic Data Interchange (EDI) document from a requester using a wireless mobile hand-held device according to the present invention and employs a corresponding data table that is resident on a supplier's Web-server, to perform the request and return the "response" as an EDI document to the requester. A flow chart of this process is illustrated in FIG. 4.

Although we have described the use of the invention in connection with the obtaining, inventorying, ordering, supplying and tracking of tissue and implants, the system may be utilized in other environments, for example, to track pharmaceuticals through a distribution network, including manufacturer through patient use.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described here in above. Rather, the scope of the present invention is defined only by the claims that follow.